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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/001,469	10/31/2001	Aya Jakobovits	511582002420	3304

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EXAMINER	
DAVIS, MINH TAM B	

ART UNIT	PAPER NUMBER
1642	

DATE MAILED: 12/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/001,469	JAKOBOVITS ET AL.	
	Examiner	Art Unit	
	MINH-TAM DAVIS	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 September 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *48,50 and 54-56* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *48,50 and 54-56* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Applicant cancels claim 53, and adds new claims 54-56, that are related to claims 48, 50 and are not new matter.

Accordingly, claims 48, 50, 54-56 are examined in the instant application.

The following are the remaining rejections.

OBJECTION

Claims 48, 50, 54-56 are objected to for the use of the language "101P3A11(SEQ ID NO:2866)" in claim 48. It is not clear whether 101P3A11 is the sequence of SEQ ID NO:2866, or whether SEQ ID NO:2866 is one among different 1013A11 proteins. This objection could be obviated by replacing "101P3A11(SEQ ID NO:2866)", for example, with "the 101P3A11 which is SEQ ID NO:2866".

REJECTION UNDER 35 USC 112, SECOND PARAGRAPH, NEW REJECTION

Claims 48, 50, 54 are indefinite for the use of the language "activity" in claim 48, which does not set forth the metes and bound of the claimed invention. It is not clear what type of activity is referred to.

REJECTION UNDER 35 USC 112, FIRST PARAGRAPH, ENABLEMENT

1. Claims 48, 50, 54-56 are rejected under 35 USC 112, first paragraph, because **the specification is not enabled for a method for identifying an agent that decreases 101P3A11 protein activity, or a method for identifying an agent that decreases 101P3A11-mediated ERK phosphorylation, or 101P3A11-mediated cAMP accumulation**. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claims 48, 50, 54-56 are now amended to recite a method for identifying an agent that decreases 101P3A11 protein activity, or a method for identifying an agent that decreases 101P3A11-mediated ERK phosphorylation, or 101P3A11-mediated cAMP accumulation.

It is noted that since there is no definition of "101P3A11 protein activity" in the specification, one does not known what activity is referred to in claim 48.

Claim 48 is not enabled because one does not know how to use the claimed method, in view that one does not know which activity is referred to, and thus one does not know how to determine the dimunition of said activity.

Further, the specification discloses that 101P3A11 phosphorylates an extracellular-signal-regulated kinase ERK in vitro, in prostate cancer cells in culture, and that a MEK-1 inhibitor inhibits the 101P3A11 mediated ERK phosphorylation in vitro, in prostate cancer cells in culture, indicating that the MEK-ERK cascade is involved in vitro (specification, pages 133-134).

One cannot extrapolate the teaching in the specification to the enablement of the claims. At most the data indicates that 101P3A11 regulates a kinase ERK in vitro. However, there is no indication that the 101P3A11-ERK pathway is involved in regulation of transcriptional factors or proliferation diseases. Although pathway such as the Ras/Raf/MEK-ERK could be associated with regulation of transcription factors in vitro (Chang F et al, 2003, Leukemia, 17: 1263-1293), it is not clear what the in vivo targets of the ERK that is phosphorylated by 101P3A11 are, because ERK is a kinase and could have different, numerous targets, and would not necessarily regulate transcriptional factors, and because there are different ERKs, and it is not clear that the ERK that isphosphorylated by 101P3A11 are similar to the ERK1 and ERK2 phosphorylated by the Ras/Raf/MEK-ERK pathway.

Similarly, although the specification discloses that 101P3A11 increases cAMP accumulation in prostate cancer cells in vitro, it is not clear what the results, especially in vivo results, of accumulation of cAMP by 101P3A11 are.

Thus, since one cannot predict what the targets are of the ERK phosphorylated by 101P3A11, nor what the in vivo effects are by the accumulation of cAMP by 101P3A1, **one would not know how to use the agents identified by the claimed method.**

Further, one cannot predict that in vitro data would be correlated with in vivo data, due to possible homeostasis, which is absent in in vitro assay. For example, Hummler E et al, 1994, PNAS, USA, 91: 5647-5661 teach that there is compensation within the CREB/ATF family of transcription factors, wherein mice with disruption of the

CREB gene appear to be healthy, and has an increase level of CREM, another member of the CREB/ATF family , and no change in the level of ATF1. Hummler E et al conclude that CREB is not the sole mediator of camp-dependent transcriptional regulation, and probably acts in concert with a specific subset of camp responsive element-binding proteins to transduce the camp signal and in its absence, these same proteins can compensate for CREB function. Similarly, Xu Xin et al, 2001, FASEB J, 15(4): A313, teach that compensatory mechanism could regulate apoptosis to overcome the low induction of Fas and FasL in activated CD4+ cells of IRF-1 null mice.

In view of the above, one cannot predict that the inhibitors of 101P3A11-mediated ERK phosphorylation, or the inhibitors 101P3A11-mediated cAMP accumulation would be of any use in vivo, and thus one would not know how to use the inhibitors identified by the claimed method.

2. If Applicant could overcome the above 112, first paragraph rejection, claims 48, 50, 54-56 are still rejected under 112, first paragraph, because "101P3A11" encompasses variant 101P3A11 proteins, for reasons already of record on paper of 06/16/04.

Applicant argues that the term "101P3A11" in claim 48 is now defined by SEQ ID NO:2866.

Applicant's arguments have been considered but are found not to be persuasive because it does not appear that 101P3A11 as recited throughout the claims has been defined as SEQ ID NO:2866.

The rejection could be obviated, by amending the claim 48, for example, to add at the end of the claim, "wherein 101P3A11 is SEQ ID NO:2866".

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MINH-TAM DAVIS whose telephone number is 571-272-0830. The examiner can normally be reached on 8:30AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, JEFFREY SIEW can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MINH TAM DAVIS

December 01, 2004

SUSAN UNGAR, PH.D
PRIMARY EXAMINER